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Task Force Report

The legal implications of medical guidelines — a Task Force of the European Society of Cardiology

P. J. Schwartz*, G. Breithardt†, A. J. Howard‡, D. G. Julian§ and N. Rehnqvist Ahlberg‖

**Department of Cardiology, Policlinico S. Matteo IRCCS and University of Pavia, Pavia, Italy; †Westfälische Wilhelms, Universität Münster, Medizinische Klinik und Poliklinik, Münster, Germany; ‡European Society of Cardiology, Sophia Antipolis, France; §London, U.K.; ‖The National Swedish Board of Health and Welfare, Stockholm, Sweden*

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Lady Thatcher: *They are exactly what they say, guidelines, they are not the law. They are guidelines.*
Ms Baxendale: *Do they have to be followed*?
Lady Thatcher: *Of course, they have to be followed, but they are not strict law. That is why they are guidelines and not law and, of course, they have to be applied according to circumstances*[1].

Introduction

Medical care varies markedly within Europe. Despite the availability of the same scientific information, there is frequently a lack of uniformity in the management of patients affected by cardiovascular diseases. Medical guidelines have gained widespread recognition because they have the potential of improving the education of medical personnel and, thereby, producing higher standards in delivery of care. However, this desirable outcome will only be achieved if they are, indeed, implemented.

The European Society of Cardiology (ESC) considers the improvement of clinical practice as one of its major obligations. It has regarded the level of implementation of medical guidelines as insufficient. This may be due to multiple reasons including insufficient dissemination, lack of uniformity among guidelines produced by different bodies, and sometimes by their distance from clinical reality. Last, but not least, by many physicians there is a perception that guidelines may interfere with their clinical freedom and a concern about the potential legal implications from following or not such recommendations.

The ESC has considered various means of promoting guidelines. A difficult question is whether or not the existence of legal implications may influence their implementation. These questions prompted the ESC to institute a Task Force with the objective of enabling its members and other interested parties to understand the implications of guidelines, including the potential legal liabilities to which the authors and users could be exposed.

Therefore, the main purpose of this Task Force has been to review the legal and social implications of medical guidelines. The present document summarizes the discussions between the members of the Task Force and reflects their consensus.

The role of the ESC

The ESC has long been aware of the significance of guidelines for medical practice and of the need to have appropriate procedures to develop them. In 1994, it created the Committee for Scientific and Clinical Initiatives (SCI) that has the responsibility of initiating Task Forces which have, among their objectives, the preparation of guidelines and addressing their implications[2]. Task Forces should represent a broad spectrum of expertise in the speciality which may also come, where appropriate, from disciplines outside cardiology. Necessary care is given to the composition of such a Task Force, its deliberations and procedures, and to the final drafting of a report that will undergo an external review. A final recommendation from the SCI

Correspondence: Peter J. Schwartz, MD, Professor & Chairman, Department of Cardiology, Policlinico S. Matteo IRCCS, V.le Golgi, 19, 27100 Pavia, Italy.

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Committee is given to the Board of the ESC for acceptance of the document, which will then be published in the *European Heart Journal*. These procedures are intended to guarantee the most objective development of guidelines issued in the name of the Society and to create the framework necessary for coherence between European and national guidelines.

Definition of guidelines

The medical community in general and specialist groups, such as cardiologists in particular, have recognised the importance of guidelines as living, dynamic information or communication tools intended by the authors to assist practitioners in optimizing the care of their individual patients. Unfortunately, there has been little focus on the precise definition or meaning of the term 'guidelines' ; what is more, there are a number of related words or concepts that overlap with guidelines and blur the edges of precision. As discussed later, the law has a growing interest in the field of guidelines, especially as related to clinical practice, so some clarity does need to be brought to this topic. Four examples of partly different definitions are given.

The 28th Bethesda Conference[3] provided specific definitions of a variety of guidelines: Guidelines; Healthcare Guidelines; Clinical Practices Guidelines; Care Plan; Care Module; Clinical Pathway. Guidelines were defined as '*a related set of generalizations derived from past experience arranged in a coherent structure to facilitate appropriate responses to specific situations*'. A Clinical Practice Guideline was defined as '*A guideline developed to aid practitioner and patient pursuit of the most appropriate healthcare responses to specific clinical circumstances*'.

In a book published in the U.K. in 1998, Hurwitz[4] described a number of related terms that are not easily distinguished from guidelines, or from each other: Protocol; Practice Policies; Medical Review Criteria; Performance Measures; Codes of Practice; Guidance. In this author's view '*Guidelines* (compared to text books) *are more concerned with specifying treatment strategies for certain patient types, with healthcare quality, and the reduction of unjustifiable clinical variability and costs*'. He also states '*that another way of looking at a guideline is as a collection of recommendations embodying certain standards of clinical management*'. Hurwitz defines Codes of Practice — which are the closest in approach to guidelines — as '*recommendations encompassing the safety and efficacy of clinical practices*' and indicates that '*codes of practice offer mechanisms for facilitating ethically acceptable and sociably sensitive practice*'.

The US Institute of Medicine[5] viewed guidelines as '*systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances*'.

The US Evidence-Based Medicine Working Group defined Guidelines[6]. '*Guidelines . . .like overviews . . . gather, appraise and combine evidence. Guidelines, however, go beyond most overviews in attempting to address all the issues relevant to a clinical decision and all the values that might sway a clinical recommendation. Like decision analysis, guidelines refine clinical questions and balance trade-off*'.

It results from considering these differing wordings that the purpose of the specific documents loosely called a guideline, is key to its status as such. The guidelines family can cover the full range of topics from generalizations derived from previous experience; broad healthcare policy; defined episodes of care; measurements of care; assessment of health care quality; generic decisions on courses of action; restricted yet detailed patient management in the form of protocols.

It is important, therefore, for authors of proposed guidelines to have in mind an appreciation of the different concepts and wording involved and to define clearly the purpose of the specific document targeting a category of practitioner/reader.

It is equally important for the practitioner/reader of the document purporting to be a 'guideline' to recognise that, in fact, it could be classified as something else. This Task Force suggests that the U.S. Institute of Medicine definition set out above is the simplest to understand and use.

Legal status of guidelines

Guidelines are developed to aid the practitioner in pursuing the most appropriate healthcare response for the clinical circumstances of a specific patient. As such they may be expected to be up-to-date in terms of medical science, highlighting critical clinical information and provide statements on common and accepted evidence-based medical practice. Many respected national or international physicians' colleges, associations, societies — covering general or speciality groups — are developing and publishing guidelines written by recognised experts and they are thoroughly peer reviewed. Because of this status, guidelines have an increasing significance in the legal arena.

It is worth noting that guidelines coming from organizations such as the ESC have no specific legal authority and are in no way legally binding. Nevertheless, they may have potential legal significance to the extent that they represent the state-of-the-art. As such, guidelines can serve legislators in the regulation of difficult clinical or medico-ethical activities. They may also form the basis of expert evidence adduced either for the plaintiff or the defendant in civil cases involving claims of medical negligence.

Statute law referring to guidelines

National legislators sometimes get drawn into drafting legislation (statute law) on very complex medical subject matters. It is not surprising therefore that Governments

and Parliaments turn to learned and 'independent' bodies to carry the responsibility for preparing the detailed technical documentation underpinning legislation in these areas. There are, to date, just a few situations where direct or delegated legislation has been developed in this way, and four examples from European countries are given below to illustrate differing approaches.

In the Netherlands, very strict guidelines on physician assisted death have been drawn up by the Royal Dutch Medical Association and incorporated in a legislative directive, allowing doctors intentionally to terminate the lives of their patients only if this is done in accordance with these strict guidelines. A doctor faced with prosecution can rely upon strict adherence to the guidelines as providing immunity from being found guilty of murder or manslaughter.

In the U.K. in 1990, Parliament established a special Authority, called the Human Fertilisation and Embryology Authority, to develop and enforce in vitro fertilization (IVF) techniques. The Authority proposed a carefully researched and drafted 'Code of Practice', regulating both the ethical and clinical parameters of this treatment. The Authority's decision to restrict to three the number of fertilized eggs which can be placed in a woman's uterus during treatment by IVF is a clear example of a guideline emanating from ethical, scientific, safety and cost considerations. As Hurwitz has pointed out '*This particular guideline is unambiguously clear, and its mandatory nature is made clear by enforceable penalties. Non-compliance could result in revocation of the license required to practice IVF treatment*'[4].

Both of these guidelines carry the force of law but have been criticised as being too restrictive and as such potentially harmful to the treatment of some categories of patient.

In France, since 1993, many practice 'Guidelines' have been introduced, having been developed under the responsibility of an independent agency for the development of medical evaluation. What is interesting to note is that these guidelines which cover investigation, prescribing and certain medical procedures, were developed by an independent body and are backed up by fines for non-compliance. In reality, however, this is an unlikely event.

In Germany, the second Health Care Reform Law (2nd GKV-Neuordnungsgesetz) states in paragraph 137a Abs. 2 that for medical activities of which the quality should be ascertained, the Federal Chamber of Physicians should determine the necessary quality assurance programmes. In the accompanying comment, it is not explicitly stated who will be included in the development of such requirement. However, as an example, specialty medical societies are cited. Guidelines issued by professional medical and/or scientific organizations do not have a direct legal status in Germany. However, they may easily gain an indirect legal character (mittelbare Verrechtlichung) if the courts determine that they represent standards of care for medical practice. This would mean that if a physician does not follow such guidelines in a specific situation, there might be a strong requirement to justify any deviation from the established standard.

The trend to issue guidelines based on statute law directly or on delegated legislation developed via State agencies can be expected to continue and increase in Europe. In many ways, such guidelines have better credibility with the public in that they are generally well researched and based on all available expert opinion. However, the same challenge remains with quasi legal guidelines as with other guidelines; namely, keeping these up to date and current with both modern and evolving science and public opinion.

Negligence claims based on guidelines

The differing national approaches to the law of tort (negligence) whether based on common law, the Code Napoleon, or with origins in Roman law, indicate important differences in determining the burden of proof; the role of precedent; the admissibility of evidence — all this militates against a country specific analysis. It is not possible in a general article such as this to do justice to this topic on a pan European level. Nevertheless, an illustration will be given.

In common law systems, such as exist in the U.K. and U.S., a plaintiff's claim as to negligence in medical practice is to be found in proving three key matters: that the plaintiff was owed a duty of care (and this is generally the case in patient/doctor relationships), that this duty was breached by failure to provide the required standard of care, and that the plaintiff was actually caused harm by this failure.

Every claim of negligence is determined according to the facts of each individual case and by the weight of evidence and the credence that can be given to evidence tested in court. Therefore, it is in the area of the presentation of evidence relating to the required standard of care — a reasonable test — in every case, that may lead to the consideration and review of a guideline and its applicability.

The Hurwitz book reviews a number of cases brought before English Courts[6] and discusses a number of key questions:

- Does the existence of Protocols and Guidelines affect the standard of care required under the law of negligence?
- Does deviation from guidelines constitute negligence?
- Can adherence to guidelines protect doctors from liability?
- What if there is a lack of professional consensus or 'competing' guidelines?

His conclusion is: '*The mere fact that a Protocol or Guideline exists for the care of a particular condition does not of itself establish that compliance with it would be reasonable in the circumstances, or that non compliance would be negligent. As guideline-informed health care increasingly becomes customary, so acting outside the*

guidance of guidelines could expose doctors to the possibility of being found negligent, unless they can prove a special justification in the circumstances'.

One final example to underline this point will be given, this time from the U.S.A.

In a case involving a patient with chest pain who developed a coronary artery aneurysm as a result of vessel wall laceration during coronary catheterization and requiring emergency bypass surgery, the guidelines of the ACC provided objective, inculpatory evidence against the cardiologist who was sued for performing a procedure that was not medically indicated. Prior to the catheterization, the patient had a normal resting electrocardiogram and no exercise test was done. The guidelines of the ACC state that mild, stable chest pain or atypical chest pain alone does not warrant catheterization.

Socio-economic aspects of guidelines

In generating guidelines, authoritative bodies such as the ESC, should provide information on what is considered to be the most effective management of a specific clinical situation based on evidence of the highest quality. In reality, in many countries economic considerations determine the level of health care achieved. Particularly in cardiology, the gap between what is medically possible and the resources available is increasing rapidly—not so much due to reduction in resources as to an escalation in the number and types of effective treatments available. Coronary bypass surgery in octogenarians and implantable cardioverter defibrillators are good examples of successful therapies whose use is frequently limited on economic grounds. Most of these advances substantially improve the quality and/or length of life and can be considered 'cost-effective', but they may increase rather than reduce expense.

Increasingly, health management organizations are seeking to restrict spending and are in danger of developing protocols which recommend levels of care which may not be acceptable to patients or the profession. Guidelines may be of considerable value to the public as well to cardiologists by indicating the minimum standards that should be observed. In this context, the failure of health providers to achieve such a standard might well have legal consequences, but guidelines must not lead to unrealistic expectations.

Medical discretion

Guidelines represent the state-of-the-art (based on clinical trials and expert knowledge) of effective and appropriate patient care at the time of their creation. Guidelines cannot be appropriate for all clinical situations. The decision to follow or not follow a recommendation from a guideline must be made by the physician on an individual basis, taking into account the specific conditions of the patient. Guidelines may be considered as a corridor which helps physicians to separate necessary from unnecessary items. Deviations from guidelines for specific reasons are possible. Guidelines should not be understood as restrictions of therapeutic freedom but they should be considered as a chance for orientation in a health care system characterized by rationalization and rationing.

Authority and validity of clinical guidelines

There is a need to agree on how guidelines are created ('guidelines for creation of guidelines'). The process of development of guidelines needs to follow specific criteria to ensure appropriate quality and several key attributes of good guidelines have been suggested[6–8].

Face credibility

Face credibility is the credibility accorded to the guidelines by the relevant user groups. The guidelines of the European Society of Cardiology will be credible to the European cardiologists, for whom they are designed, provided that those who generate them are respected for their expertise, and represent a wide range of subdisciplines and the diverse cultures of the Continent.

Validity

The validity of guidelines can only be evaluated by determining whether they lead to the better management and outcome of patients. The Society should encourage studies, such as EUROASPIRE[10] and its evolution (Euro Heart Survey), that determine whether its guidelines are followed by improvements in practice and that may lead to further improvements in the drafting of guidelines.

Reproducibility

Many different organizations are now involved in developing guidelines. In the case of cardiology, they are being produced by national Cardiac Societies, by pharmaceutical companies (directly or indirectly), by Government agencies, by the World Heart Federation and others. Inconsistency between the different guidelines leads to confusion and lack of credibility. Inevitably, some discrepancies will occur because of different audiences and conditions, but attempts should be made to review guidelines from the various authorities before generating new ones, and efforts made to achieve consensus.

Representativeness

It is important that those who develop guidelines are free from bias and are seen to be so. The members of the Society's Task Forces are an élite and guidelines should take into account the views and experience of those without the resources to which leaders in the field are likely to have access. Furthermore, as the membership of

the Society is confined to those involved in cardiology, the advice of those in general medicine, other medical specialities, and healthcare generally should be obtained.

Clinical applicability and flexibility
As Hurwitz has pointed out, guidelines should '*pertain to significant health problems and specific patient groupings, defined in accordance with scientific, medical and health economic criteria. Identification of valid exceptions to recommendations, and suggestions for how patient preference can be incorporated into decision-making will help to ensure that guidelines allow for appropriate flexibility of application*'[4].

Clarity
Clarity is essential. Ambiguity and imprecision must be avoided. However, in order to avoid limiting clinical freedom, the recommendations may deliberately not be prescriptive in a specific context, even when it would be appropriate for them to be so. This may be undesirable because it may imply that other approaches are equally acceptable even though the evidence indicates otherwise.

As the lingua franca of the Society is English, they must be written impeccably in that tongue. When the final draft of a guideline is being prepared, special attention should be paid to the correctness of its English, so that its meaning is clear not only to native English speakers (including Americans) but also to those whose first language is not English.

Reliability
It is essential that guidelines are interpreted by different health professionals in different environments in the same way. This is best established by having an extensive review prior to completion.

Transparency
In order to establish the authority of guidelines, it is necessary that the process by which they were generated is made public. Thus, the final document should include not only the names of the Task Force members and the way that they operated, but the organizations and individuals consulted, and the use made of evidence-based and opinion-based information.

Scheduled review
To maintain the authority of guidelines, it is essential that they are updated at appropriate intervals. This interval will vary dependent on the rate at which fresh information is forthcoming in the relevant field. It is proposed that a complete revision of an ESC guideline should be undertaken at intervals of not less than 3 and not more than 5 years. However, each year, the Chairman of the relevant Task Force should be consulted as to whether addenda should be added in the light of important new research. It is suggested that no Chairman should serve in this capacity for more than two editions, and that the composition of Task Forces should be partially changed (perhaps by half its members) for each edition.

Dissemination

For guidelines to impact on clinical practice they have to be widely disseminated. The way this will be accomplished would benefit from co-operation of the National Societies.

The Task Force is fully aware that several limitations and obstacles exist which will hinder uniform implementation of medical guidelines throughout Europe. It is indeed not realistic to expect that different countries, with profound regional differences in their clinical approach and even more in the preferential use of certain drugs, will adhere strictly to a European guideline.

The Task Force recommends transmitting new guidelines to the National Societies of the Members States which will then be encouraged to have them translated into the relevant languages. It is understood that each National Society may wish to, or must, introduce specific amendments to the guidelines in order to adapt them to local situation. Whenever this happens, it should be clearly indicated in the text. Once translated and/or amended, it is hoped that the National Societies should publish them in their official journals. In this way, cardiologists throughout Europe will have a good opportunity to read the guidelines or to prepare their own guidelines, but ensuring that they are compatible with those of the ESC.

Although the primary audience of the ESC guidelines is cardiological, it is intended that they should be distributed by the National Societies to their Ministries of Health, with the goal of having them sent to hospital administrations and to other health care providers. Furthermore, the guidelines should also be sent to the directors of the Training Programs in Cardiology to ensure that they will become part of teaching courses.

Summary

Health purchasers, providers and patients all require advice if the best medical care is to be given, when resources are finite. Guidelines are systematically developed statements to assist practitioners and patients in decisions about appropriate health care for specific clinical circumstances. They have a potentially important role in summarizing the strength of evidence for the effectiveness of particular treatment strategies in a specific clinical context, in relation to risks and costs.

The Task Forces of the ESC are well placed to provide recommendations in relation to the prevention and treatment of heart disease because of the widely based expertise of its members. The information that the Society provides should be of value to National Societies, and other national and regional organizations in formulating policies appropriate to local circumstances.

The guidelines from an international organization, such as the ESC, have no specific legal territory and have no legally enforcing character. Nonetheless, in so far as they represent the state-of-the-art, they may be used as indicating deviation from evidence-based medicine in cases of medical negligences or, vice versa, as indicating adherence to evidence-based medicine in cases of questioned liability.

The diversity of national systems of education, health care and provision, living habits, and cultural background among the many European countries ask for careful adaptation to the regional and national peculiarities. Adaptation to regional differences may have a strong impact on the strength with which guidelines will be applied by practising physicians. It seems straightforward that the closer the issuing organ is to the recipients, the greater is the chance that the guidelines will be accepted. This might also imply stronger legal impact than if guidelines are coming from far distant organs.

The creation of guidelines requires that the available scientific knowledge is correctly interpreted and outlined (validity); that other expert groups to whom the same scientific information is available, would come up with approximately the same recommendations (reproducibility); that all important disciplines have contributed to the development of a guideline (representativeness); that the target group for which the guideline is intended is clearly defined (clinical applicability); that guidelines use precise definitions (clarity); and that there is an exact documentation on how these guidelines were developed. Furthermore, guidelines should contain information on how and when they will be re-assessed, i.e. how long they will be valid and how their acceptance in medical practice is implemented and assessed. The more the process of development of guidelines follows these quality criteria, the greater will be their potential impact on the quality of care.

This report has been reviewed by members of the Committee for Scientific and Clinical Initiatives, Members of the Board of the European Society of Cardiology, and by one external reviewer. Final approval was given by the Board of the European Society of Cardiology on 17 April 1999.

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